

REMARKS

Applicant's counsel thanks the Examiner for the careful consideration given the application and for the courteous telephone interview conducted on August 9, 2010 between applicant's undersigned counsel, Examiner Sasan and SPE Robert Wax. During the telephone interview, applicant's counsel discussed proposed amendments to claim 1; those amendments have now been incorporated into claim 1 as set forth above. In claim 1, lines 2-3, when it states "and distinct from said first layer", this means that the material of the second layer is different from the material of the first layer. The substance of the telephone interview is as follows.

Applicant's counsel first summarized the problem to be solved by the invention. It has been known for a long time that it is difficult to get the physiologically active substances, such as choline chloride, into the abomasum of a ruminant, where it can be absorbed. The problem is that the physiologically active substance will first remain in the rumen of the ruminant for an extended period of time, where it is hot and moist. Choline chloride and many physiologically active substances are very deliquescent or hygroscopic and thus quickly absorb moisture in the rumen and dissolve and are degraded so they are not available in the abomasum. What is needed is a "rumen bypass" particle, that is, a particle which passes through the rumen without being decomposed or degraded and thereafter arrives in the abomasum, where it can be dissolved and absorbed so that the physiologically active substance can be effectively utilized by the ruminant. It has been known for a long time to coat the particle of physiologically active substance with a lipid, such as vegetable oil, to protect the substance from decomposition/degradation in the rumen; this is known as rumen bypass and an example of this technology is US 4,948,589.

Applicant's counsel also explained during the interview the critical innovation of the present invention. The present inventors discovered that, when you take a traditional rumen by-pass particle (having a core with the physiologically active substance and a first coating layer of a hydrophobic lipid, such as vegetable oil) and pelletize material including the particles in a pelletizer, the first layer would be cracked or abraded or rubbed off or otherwise damaged or compromised so that it could not effectively do its job of protecting the core (hygroscopic material) from attack by the humidity in the rumen. The present inventors discovered that the solution to this problem was to apply a second layer of carnauba wax over the first layer. The second layer of carnauba wax was hard enough and tough enough to protect the first layer from

degradation during the pelletization process. They discovered that it was critical to the success of the invention to have two layers, each layer of a particular material; the first layer consisting essentially of a hydrophobic substance selected from the group consisting of vegetable oils, hydrogenated vegetable oils, stearic acid and mixtures thereof; the first layer is to serve the traditional purpose of rumen by-pass, that is, to protect the hygroscopic core material from humidity attack in the rumen; the second layer, consisting essentially of carnauba wax, was needed to effectively protect the first layer and the core from degradation from abrasion, pressure, and mechanical and thermal stress encountered during the pelletization of the particles into an animal feed pellet.

During the interview, applicant's counsel also described the applied references. First, Iijima, et al. (US 4,948,589) was discussed; this teaches the original rumen by-pass technology, that is, a core of physiologically active substance which is hygroscopic, coated with a first layer of a lipid, such as vegetable oil or wax; all of this is discussed at column 1 lines 7-47 and column 3 lines 34-40 and 50-56. However, this reference does not say anything about adding any additional layers, such as a second layer to protect during pelletization.

The next reference discussed was Spires (US 4,394,377). This reference simply teaches the fact that dietary choline for animals can be combined with antibiotics and pelletized for animal feed purposes. However, this reference does not add any coating layers prior to pelletization. As discussed during the interview, Spires refers to a different way to address and solve the problem of how to administer choline in a rumen resistant effective way. In order to avoid degradation of choline in the rumen, choline is administered together (or before or after) with a propionate-enhancing antibiotic compound because this compound (being an antibiotic) reduces the degradation activity of bacteria present in the rumen. Applicant does not agree with the statement at page 5 of the Office action since Spires does not describe a feed pellet comprising choline compressed together with animal feed. Spires states only that "These compositions [i.e. choline plus antibiotic] may be prepared in dry granular powder form, as pellets," (column 13, lines 20-21) and that "choline and the subject antibiotic materials may be incorporated directly into feeds by a mill or other feed supplier to provide a finished feed product to the grower." (column 14, lines 34-37). These passages mean that choline plus antibiotic (not choline plus antibiotic plus animal feed) can be shaped into a pellet and that they can be mixed (not pelletized) with animal feed. Nothing is said in the patent about subjecting the mixture of choline plus antibiotic plus animal feed to a pelletization process to give animal feed in pellet

form containing choline. Moreover, choline and the antibiotic are not coated with anything. Nothing is said about a core comprising choline and a binder and a possible coating of such a core. This is no wonder since the problem of administration of choline in a rumen resistant way is addressed and solved in a different way, namely, by co-administration of choline and an antibiotic. Further, the problem of proving a formulation for administration of choline that retains rumen by-pass properties even after pelletization with animal feed is not at all indicated or discussed in Spires since Spires's invention is directed to a completely different solution with respect to the present invention. Spires is not directly on point and when combined with the disclosure of Iijima or Ito would not suggest the present invention.

The next reference discussed was Ito et al. (US 6,299,912). This reference is not directly on point, since the core material, L-ascorbic acid-2-phosphoric ester salt, has very low solubility in water, and thus is not a hygroscopic material particularly susceptible to humidity attack in the rumen. Nonetheless, it does teach to coat the ester salt with a digestible and non-hydrophilic coating, such as vegetable oil or wax (column 5 lines 1-17), much like the traditional rumen by-pass layer discussed above. In this regard, '912 is like all the other conventional or traditional rumen by-pass patents which teach a single layer of hydrophobic substance coating to protect the core from humidity attack in the rumen. '912 does mention, among many other processes, the option of pelletizing the particles into an animal feed pellet (column 6 lines 36-67). However, it makes no mention of any additional or second coating to protect the particle from degradation during the pelletization process. Applicant would also like to point out that although Ito says that the preparation containing L-ascorbic acid-2-phosphoric ester salt can be administered to cattle in general, nothing is said in the patent regarding ruminants or rumen by-pass problems. This is not surprising, since the composition was especially studied and made for supplying fish (such as Japanese river trout, carp, sea bream, salmon, etc.) with L-ascorbic acid-2-phosphoric ester salt. These fish are grown at a high density within a short time, therefore, stress is readily generated and the demand for ascorbic acid is high. Therefore, the preparation of Ito is especially indicated for the nutrition of small animals that are bred at a high density. The preparation of Ito is not at all directed to ruminants, which are big animals bred in a different way and with different nutritional problems. Accordingly, Spires and Ito are not relevant to the present invention and therefore it cannot be said that they suggest or motivate the present invention in combination with Iijima, which is the only document directed to formulations for choline administration to ruminants. However, Iijima describes only a single coating of vegetable oil or wax and there is nothing in the other two documents to suggest that the single

coating should be coated with another layer of hard wax in order to obtain a formulation that retains its rumen by-pass properties even after pelletization with animal feed.

In summary, the relevant prior art references teach traditional or conventional rumen by-pass technology, that is, producing a core of physiologically active substance plus binder, the physiologically active substance usually being hygroscopic, and coating the core with a first layer of a hydrophobic substance typically vegetable oil or wax, to protect the core from humidity attack in the rumen so that the core can pass through the rumen without being dissolved/degraded and arrive in the abomasum, where it can be absorbed and utilized by the ruminant. None of these prior art references saw the problem which the present inventors have discovered, that is, that the first layer of coating can be cracked/abraded, degraded, rubbed off, etc. during the pelletization process, thus exposing the core to humidity attack. The present inventors have uniquely discovered the solution to this problem, that is, coating this first layer with a second layer of carnauba wax, which is tough enough and hard enough to protect the first layer from degradation during the harsh pelletization process.

Since the present inventors have recognized the problem not recognized previously, that is, the need for a protective second layer to protect the first layer during pelletization, and have also come up with a solution to this problem, that is, providing a second layer consisting essentially of carnauba wax effective to protect the first layer from degradation from abrasion, pressure and mechanical and thermal stress encountered during pelletization of the particles into an animal feed pellet, it is clear that the present invention is an important and dramatic advance over the prior art and is accordingly patentable subject matter. Since the present inventors have come up with an important advance in the field of rumen by-pass, which is not shown or obvious from the prior art, it is clear that claim 1 is now allowable. All the other claims are dependent or otherwise include the limitations of claim 1 and accordingly are allowable by reason of their dependency.

As was discussed during the interview, applicant's counsel is also enclosing herewith an executed Declaration, which is signed by Emilio Cerchiani. The subject matter of the Declaration was gone over during the interview. The Declaration describes certain experiments which were conducted to demonstrate the criticality of having two layers, the first layer consisting essentially of a hydrophobic substance selected from the group consisting of vegetable oils, hydrogenated vegetable oils, stearic acid and mixtures thereof, the second layer

consisting essentially of carnauba wax. As described in the second and third pages of the Declaration, four different animal feed pellets (paragraphs 5-8 on pages 2-3) were prepared, which were the same, except that, for the first pellet, the granule had a single layer essentially made of carnauba wax; for the second pellet, the granule had a single layer made of a 50/50 weight percent mixture of (a) hydrogenated palm oil and (b) carnauba wax; for the third pellet, the granule had a single layer essentially made of lipids (hydrogenated palm oil); for the fourth pellet, the granule was the present invention, having two layers, the inner layer essentially made of hydrogenated palm oil and the outer layer being essentially made of carnauba wax.

The test results are shown on page 4 and the results are described in paragraph 5 of page 4, wherein it states as follows:

"The test results of Table 1, above, demonstrate that it is critical to have 2 separate and distinct layers, the first or inner layer being a lipid layer to provide effective rumen protection (bypass) and a second or outer layer being a hard wax layer to provide protection from the harsh pelletization process. This can be seen from the last four items of Table 1, being the four different pellets. The pellet having just a single layer of hard wax (MLC 2° Pellet) showed poor resistance (21.00%). The pellet having a single layer coating made of a mixture of hard wax and lipids (MIX Pellet) also had poor resistance (16.40%). The pellet having only a single layer of lipid (MLC 1° Pellet) also had poor resistance (22.86%). Only the pellet having two separate layers, the inner layer being lipid coating and the outer layer being hard wax coating (MLC Pellet) had excellent resistance (83.55%). In summary, all three of the single layer pellets (single layer of hard wax, single layer of a mixture of hard wax and lipid, and single layer of lipid), all showed poor rumen resistance (by-pass). Only the double layer pellet (MLC pellet) having an inner layer of lipid and an outer layer of hard wax, showed good rumen resistance."

The Declaration also tested the four different granules before they were pelletized. These results are discussed in paragraph 6 on page 5 of the Declaration, which states as follows:

"The tests of the four granules (the first four items tested in Table 1) show that, for granules that have not been pelletized, a granule having a layer of lipid next to the core will provide effective ruminal resistance. The MLC 1° granule has a single layer of lipid and showed 86.50% resistance and the MLC granule (inner layer of lipid and outer layer of hard wax) also showed good resistance (87.80%). The MLC 2° granule has only a single layer of hard wax and showed poor resistance (28.15%); the MIX granule has a 1:1 by weight mixture of lipid and hard wax but showed poor resistance (35.10%). It is important to note that when the granule with a single layer of lipid (MLC 1°) is tested as a granule, it has good resistance (86.50%), but when it is pelletized without a protective second layer of hard wax, the performance is very poor (MLC 1° pellet has resistance of 22.86%). However, when the two layer (MLC) granule is pelletized, very little resistance is lost (from 87.80% for MLC granule to 83.55% for MLC pellet). In summary, it is critical to have two different layers, the first or inner layer being a lipid layer and a second or outer layer being a hard wax layer, in order to provide a pellet having effective rumen protection. None of the single layer granules (single layer lipid, single layer hard wax or

single layer mixture of lipid and hard wax) can provide effective rumen protection when put into pellet form."

In summary, the Declaration convincingly shows that it is critical to have two different layers, the first or inner layer being a lipid layer, and a second or outer layer being a hard wax carnauba layer, in order to provide a pellet having effective rumen protection. None of the single layer granules (single layer lipid, single layer hard wax, or single layer mixture of lipid and hard wax) can provide effective rumen protection when put into pellet form.

When all of the foregoing evidence is considered, the only conclusion which can be drawn is that the claims as now presented define over the prior art and are in condition for allowance. At the conclusion of the telephone interview, the Examiners stated that, based on the argumentation during the interview, the claims as now presented appeared to define over the art of record. For all the foregoing reasons, it is believed that claim 1 as now presented is in condition for allowance, which is respectfully requested. All the other claims are dependent claims or otherwise include all the limitations of the main claim, and are accordingly also in condition for allowance.

If any further issues arise, the Examiner is requested to contact the undersigned counsel by telephone so that any open items can be resolved. If any further fees are required by this communication, please charge such fees to our Deposit Account No. 16-0820, Order No. BUG5-36500.

Respectfully submitted,
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Date: August 24, 2010